FACT SHEET: CMS RESPONDS TO STAKEHOLDER FEEDBACK REGARDING COVERAGE WITH EVIDENCE DEVELOPMENT

Overview: *In the past, the Centers for Medicare & Medicaid Services (CMS) has been unable to cover certain medical services, items, or devices through a national coverage determination due to lack of sufficient data about the appropriateness of these technologies for coverage under the Medicare program. However, under CMS' coverage with evidence development (CED) initiative, CMS may be able to extend coverage under these circumstances with the collection of additional data.*

While this data is central to CMS' efforts to ensure that the care beneficiaries receive is reasonable and necessary, CMS is also committed to ensuring that Medicare patients can benefit from advances in medical technology.

CMS' announcement today addresses some of our stakeholders' questions about the CED initiative, including how CMS intends to extend CED principles to its existing coverage determination process.

Background: On April 7, 2005, CMS released a draft guidance document on the process for an alternative approach to making Medicare coverage decisions—known as coverage with evidence development (CED). The document is available online at http://www.cms.hhs.gov/coverage/download/guidanceced.pdf.

CMS issued the guidance document to explain CMS' vision for how these special types of coverage decisions will affect the existing national coverage decision (NCD) process, including how such coverage expansions can be accomplished as effectively as possible. The document described the factors that CMS may consider in deciding to expand national coverage for certain items and services in the context of prospective data collection. Most importantly, the guidance document solicited feedback from stakeholders throughout the health care industry about these topics.

During the 60-day comment period, CMS received comments from 65 organizations, including advocacy groups, medical specialty societies, trade groups, and health product manufacturers. Some comments expressed concerns about CED because the draft guidance document did not provide specific information. CMS plans to release a second draft guidance document that will provide more information about CED and address the questions and concerns raised by the public. However, to continue CMS' dialog with stakeholders, this fact sheet addresses the commenters' most frequently cited concerns.

Q: When will CMS require additional evidence development as a condition of coverage? How often will CMS require evidence development in order to make national coverage determinations (NCDs)?

A: CED will be required only in the context of a national coverage determination (NCD). Not all technologies meet the requirements for consideration as a NCD. In fact, about 90

percent of Medicare's coverage policies are made at the local level. Thus, we expect that CED will be used infrequently.

In addition, as part of CMS' continuing work with stakeholders on the CED initiative, CMS looks forward to developing guidelines that describe which items and services will require additional evidence development in order to make an NCD. Proposed guidelines will be available for public review and comment in the next draft of the CED guidance document. Because these guidelines will stipulate specific circumstances under which CED will be used, we anticipate that CED will be applied in a limited number of NCDs.

Q: How will CED affect local coverage determinations?

A: Whenever CMS issues an NCD, the coverage policy is national and supersedes any inconsistent local coverage decisions. However, CMS only issues about 18-24 NCDs each year, of which only a few may require CED. The vast majority of coverage decisions are made locally. CED will only occur in the context of an NCD. For example, CMS' recent NCD for payment of off-label use of colorectal anticancer drugs in clinical trials conducted by the National Cancer Institute did not prevent local carriers from making their own coverage decisions about off-label use of these drugs. As always, the carriers will continue to make independent medical decisions while CMS is considering a new NCD.

Q: What is CMS' authority to collect data on beneficiaries in return for payment?

A: CMS collects data under a number of authorities, including the authority to collect data for payment purposes. This authority stems from the Social Security Act (§1862(a)(1)(A)). CMS uses this authority to determine whether an item or service is reasonable and necessary, based on CMS' own medical judgment. In the case of CED decisions, CMS needs data to ensure that payment is made for patient claims that meet the criteria specified in each NCD. CMS will use the data collected to determine whether an item or service was used for the appropriate reasons for the appropriate patients.

Q: If CED data are to be used for payment, how will evidence about a particular item or device continue to develop?

A: Although CMS will use the data to make payment determinations, the data will be available in a number of forms for analyses by CMS and the general public. As the results of those analyses are published in peer-reviewed literature, the CED data will contribute to the existing evidence base.

Q: How will patient privacy be protected?

A: Providers are required to inform patients about HIPAA protections during every encounter. Providers have access to protected health information for the purposes of treatment, payment, and health care operations (under 45 CFR 164.501). After CMS acquires patient data, it is protected under the Privacy Act. A Systems of Records Notice

(SOR) announces to the public that the data reside in CMS. The SOR specifies the authorized uses and conditions of use of the data.

Q: What are the guidelines for implementation of CED?

A: Commenters asked whether CMS will develop a standard, formal process for: 1) requiring CED as a condition of coverage; 2) designing methods by which the additional CED data must be collected; and 3) implementing CED principles. CMS is planning to issue more specific criteria for applying CED in the next draft guidance document. We look forward to further interaction with the public as we develop those criteria.

While CMS plans to use CED in specific circumstances, how CED will be implemented will vary depending on the unique requirements of the associated NCD. CMS is committed to maintaining high standards for judging the quality of CED enterprises, however, the case-by-case nature of the national coverage decision-making process requires that the CED policy remain flexible in addressing implementation issues.

Q: What will CMS do with data collected under CED?

A: CMS will rely on the data to determine whether the expanded service is reasonable and necessary for each patient who is the recipient of the item or service. Once collected, CMS or the public may have access to the CED data for research.

Q: Will the CED process be transparent?

A: CMS' coverage process is open to the public. Throughout the national coverage decision-making process, the public may access CMS' coverage website for updates and draft decisions, as well as to provide public comments on open decisions. The coverage website is available at http://www.cms.hhs.gov/coverage. CMS has engaged and will continue to engage stakeholders throughout the national coverage decision-making process, including those NCDs in which CED principles are used to make decisions.

Q: Will there be a second draft guidance document? What will be the timeframe for this?

A: In response to numerous stakeholder requests, CMS will revise the CED draft guidance document and post a second draft guidance document for comments. The second draft guidance document will provide more information about CED and address the questions and concerns raised by the public. It will be posted on CMS' coverage website in the next few months, followed by a 30-day public comment period. We anticipate releasing the final CED draft guidance document by the end of the year. All comments, the second draft guidance document, and the final CED guidance will be posted on CMS' coverage web site at http://www.cms.hhs.gov/coverage. CMS also plans to hold another Open Door Forum in the near future. Specific information about the Open Door Forum schedule is available at http://www.cms.hhs.gov/opendoor/.

Q: How does CED affect FDA's role as the arbiter of the safety and effectiveness of new medical technologies?

A: If the FDA has determined that a product is unsafe or not efficacious, Medicare will not cover the item for that use. If the FDA has approved a product for one indication, but has made no determination on a different indication, CED may be particularly helpful in providing additional evidence. For the most part, CMS or its intermediaries make determinations to cover devices and drugs that have passed FDA approval. CED is unlikely to be applied to these coverage decisions. CED is intended to allow payment for services that are expansions of existing covered services. For example, CMS recently used CED principles to expand coverage for implantable cardioverter defibrillators when used as primary prevention of sudden cardiac arrest.

Q: Which technologies could involve a CED decision? Which are most likely to involve a CED decision?

A: To provide a hypothetical example, a CED decision could involve the following situations: 1) drugs in new classes with novel mechanisms; 2) therapies that may be effective only in sub-groups; 3) drugs or devices that have demonstrated major advances over prior therapies in multiple clinical scenarios, leading to a strong belief that they could benefit other patients with other conditions; or 4) treatments for which the consequences of selecting the wrong patients for treatment may be substantial.

Q. How will you assure that CED does not generate information already available elsewhere?

A: CED is intended to add to existing data, not to replace or repeat existing information. If adequate evidence for a particular service, item, and device exists, Medicare will make a coverage decision without using CED principles.

As part of its decision-making process, CMS evaluates all available studies, FDA documents, and peer reviewed articles about the specific technology in question. CMS prepares or commissions the preparation of a health technology assessment and opens all NCD topics for public comment. CMS may also hold Medicare Coverage Advisory Committee (MCAC) meetings at which the public discusses evidence about the topic under review.

If CMS determines that the evidence currently available shows there is a potential that the item/device might be reasonable and necessary for the Medicare population, but there is not enough evidence currently available to support a determination for national coverage, we would then consider applying CED.